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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/681,750	10/07/2003	Philipp Lang	2960/113	8141

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EXAMINER	
MONTANO, MELISSA ANN	

ART UNIT	PAPER NUMBER
3738	

MAIL DATE	DELIVERY MODE
05/26/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)	
Office Action Summary	10/681,750	LANG ET AL.	
	Examiner	**Art Unit**	
	MELISSA MONTANO	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 March 2010*.
2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.
3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,8,9,11-13,15-17,20,42,51,96-108,111-113 and 137-139* is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5)☐ Claim(s) _____ is/are allowed.
6)☒ Claim(s) *1,3,8,9,11-13,15-17,20,42,51,96-108,111-113, 137-139* is/are rejected.
7)☐ Claim(s) _____ is/are objected to.
8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.
10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a)☐ All b)☐ Some * c)☐ None of:
1.☐ Certified copies of the priority documents have been received.
2.☐ Certified copies of the priority documents have been received in Application No. _____.
3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/22/2010 has been entered. The previous rejection under 35 USC 112 2nd paragraph is withdrawn in light of applicant's amendments.

Response to Arguments

2. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Inventorship

3. In view of the papers filed 11/12/2009, the inventorship in this nonprovisional application has been changed by the deletion of Hacene Bouadi, David Miller, Barry Linder, Cecily Anne Snyder.

The application will be forwarded to the Office of Initial Patent Examination (OIPE) for issuance of a corrected filing receipt, and correction of Office records to reflect the inventorship as corrected.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1, 3, 8, 9, 11-13, 15-17, 20, 42, 51, 96-108, 111-113, and 137-139 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 3,816,855 to Saleh (Saleh) in view of US Patent Application Publication No. 2002/0059049 A1 to Bradbury et al. (Bradbury).

Regarding at least claims 1 and 137-139

Saleh teaches a prosthetic knee joint device comprising a femoral component in the form of a shell member having two condylar portions with major convex bearing surfaces, which portions are bridged at one end by a portion defining a trough between the convex areas (abstract). The femoral component, particularly at least one condyle portion (11 or 12), of Saleh is shown to have a superior surface/bone-abutting surface (fig. 10) and an inferior surface/articular surface (fig. 11), wherein the superior surface/bone-abutting surface is configured to oppose at least a portion of a femur and be fixed to the portion when the implant is implanted (col. 4, lines 9-21) and the inferior surface is configured to oppose and articulate with at least a portion of a tibial implant surface when the implant is implanted (col. 4, lines 28-33), as claimed by applicant.

Saleh also teaches that the convex bearing surfaces of the femoral component simulate the femoral condyles and, in fact, it is preferred that such surfaces closely follow the natural shaping of the condyles (col. 1, lines 64-67 and col. 2, lines 1-7). However, Saleh does not explicitly teach that the femoral implant is prepared by a process comprising configuring at least a portion of the inferior surface based at least in part on one or more patient specific measurements of the patient's joint obtained from imaging data of the patient’s joint (see claim 1). Saleh also does not explicitly teach matching at least a portion of the articular surface to an underlying portion of the patient’s joint based at least in part on imaging data of the patient's joint (see claim 137), determining at least one parameter of the articular surface based on a patient-specific parameter derived at least in part on imaging data of the patient’s joint and designing the femoral implant based on the parameter (see claim 138), or determining at least one parameter of the articular surface based on a patient-specific parameter derived at least in part on imaging data of the patient's joint and selecting an implant from an electronic library based on the parameter (see claim 139).

Bradbury teaches the rapid design of biomedical devices, such as structural implants (i.e. femoral implants), using patient information and patient-specific radiological data that is captured and transmitted via a computer network to a design and/or manufacturing site (abstract). In manufacturing implants, the starting point according to Bradbury, is the patient-specific data (i.e. radiological data, patient information), obtained from various invasive or non-invasive procedures (paragraph 0052), including MRI and CT scans, as well as standard radiographs. A laser scanner may also be useful to digitize contours of an external surface. A digital model is created from the diagnostic data, which is reviewed by the physician and/or patient and modified if necessary, and then sent to a manufacturing facility (figs. 2A-2B). The biomedical devices/structural implants of the invention of Bradbury are anatomically accurate, for the purpose of providing an optimal fit with the patient’s anatomy which should promote healing (paragraph 0083).

It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the invention of Saleh to include configuring at least a portion of the implant based at least in part on one or more patient specific measurements of the patient’s joint obtained from imaging data of the patient’s joint (see claim 1), matching at least a portion of the articular surface to an underlying portion of the patient’s joint based at least in part on imaging data of the patient's joint (see claim 137), determining at least one parameter of the articular surface based on a patient-specific parameter derived at least in part on imaging data of the patient’s joint and designing the femoral implant based on the parameter (see claim 138), and determining at least one parameter of the articular surface based on a patient-specific parameter derived at least in part on imaging data of the patient's joint and selecting an implant from an electronic library based on the parameter (see claim 139), since femoral implants are known structural implants and particularly in order to provide an optimal fit with the patient’s anatomy which should promote healing, as taught by Bradbury.

The examiner notes that the claims are product-by-process claims. MPEP 2113 states: "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re*

Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). It is the position of the examiner that Saleh meets the structural limitations of the claims.

Regarding at least claims 3, 8, 9, and 11

Saleh in view of Bradbury teaches the invention substantially as claimed according to claim 1. Saleh also teaches that the femoral component can be made in any materials suited to the purpose, preferably a metal/plastics material combination (col. 6, lines 11-19). Further, materials such as metals, metal alloys, and polymers are well known in the art as suitable for use in the formation of implants. While the femoral component of Saleh can be cast from molds produced from formers which are directly molded from a natural joint, Saleh teaches that undulations resulting from the presence of cartilage should be smoothed (col. 5, lines 35-40). At least this teaching implies that the implant taught by Saleh has a thickness of a cartilage defect in a patient, as claimed by applicant. However, Saleh does not explicitly teach that the implant comprises one or more biologically active materials.

Bradbury further teaches that specific chemicals may be seeded into the implant during manufacturing, for example, growth factors, DNA, etc, for the purpose of encouraging ingrowth of bodily tissue such as bone at designated places.

It would have been obvious to one having ordinary skill in the art at the time of the invention to further modify the invention of Saleh in view of Bradbury to include one or more biologically active materials, in order to encourage ingrowth of bodily tissue such as bone at designated places, as taught by Bradbury.

Regarding at least claims 12, 13, and 15-17

Saleh in view of Bradbury teaches the invention substantially as claimed according to claim 1. Saleh further teaches that the femoral component includes studs (14) to afford good securement (col. 4, lines 15-21) and can be provided with suitably located grooves or ribbed formations, studs, spikes, stems, or other fixation formations or members (col. 6, lines 1-4). Though Saleh does not explicitly teach a peripheral structure, the examiner takes the position that it would have been obvious to one having ordinary skill in the art to include such a modification along an entire perimeter or along a portion of a perimeter of the implant, in order to afford good securement, as taught by Saleh.

Regarding at least claims 20 and 96

Saleh in view of Bradbury teaches the invention substantially as claimed according to claim 1. Bradbury further teaches a central site that determines whether the biomedical device (femoral implant) will be custom designed and/or manufactured, or whether the biomedical device (femoral implant) will be custom selected from a number of existing designs and/or manufactures (paragraph 0087). Under the customized selection on a best fit basis approach, the digital model is compared to a number of standard designs, one of which is selected for the patient on a best fit basis, and scanned in. The results of the scan are compared to the digital model to verify the product geometry and patient fit (paragraph 0091). This teaching of Bradbury meets the limitations of selecting the implant from a pre-existing electronic library of implants and that the implant is configured based on a library of pre-existing shapes, as claimed by applicant.

It would have been obvious to one having ordinary skill in the art at the time of the invention to further modify the invention of Saleh in view of Bradbury to include selecting the implant from a pre-existing electronic library of implants and/or configuring the implant based on a library of pre-existing shapes, in order to provide an implant that closely matches the patient at a lower cost than a fully customized implant (paragraph 0093), as taught by Bradbury.

Regarding at least claims 42, 97, 99, and 104

Saleh in view of Bradbury teaches the invention substantially as claimed according to claim 1. Bradbury teaches the use of CT scans, which are considered better for imaging hard tissue such as bone, to acquire radiological data from the patient for the purpose of providing an anatomically accurate device having an optimal fit with the patient's anatomy which should promote healing (paragraph 0083). Bradbury further teaches that the digital model may include patient tissue and structure surrounding the biomedical device (femoral implant), to assist in visualizing the fit (paragraph 0088). The examiner takes the position that the image data taken by Bradbury would inherently include the patient's subchondral bone when manufacturing a femoral implant and that the invention of Bradbury inherently includes designing a portion of the inferior surface of the implant to be patient-specific configured from one or more patient specific measurements.

It would have been obvious to one having ordinary skill in the art at the time of the invention to further modify the invention of Saleh in view of Bradbury to include that at least a portion of the inferior surface of the implant is configured based at least in part on image data of the patient's subchondral bone and/or is patient-specific, in order to provide an anatomically accurate device having an optimal fit with the patient's anatomy which should promote healing, as taught by Bradbury.

Regarding at least claims 100-103, 105-108

Saleh in view of Bradbury teaches the invention substantially as claimed according to claims 99 and 104. Bradbury clearly teaches the use of CT and MRI scans, among various other methods of acquiring patient radiological data (paragraph 0052). Though Bradbury does not specifically mention widths, lengths, or curvatures in specific directions and planes, the examiner takes the position that any and all of these measurements would inherently be included in the acquisition of patient radiological data as taught by Bradbury. It also would have been obvious to one of ordinary skill in the art to include measurements of width, length, and curvature in certain directions and planes, in order to ensure proper fit of the customized implant for the individual patient.

Regarding at least claims 51, 98, 111-113

Saleh in view of Bradbury teaches the invention substantially as claimed according to claim 1. Saleh further teaches that the bearing surfaces, located on the inferior/articular portion (fig. 11), of the shell member of the femoral component closely conform to the natural shaping of the corresponding parts of the knee joint (col. 3, lines 66-68 and col. 4, lines 1-4) and that these surface are held in a spaced side-by-side relation by a bridge portion (13) which appears to inherently form a varying curvature in a sagittal plane, as claimed by applicant. Saleh also teaches that the superior surface of the implant (fig. 10) is configured to be placed against a bone cut (col. 4, lines 8-21) and that the implant is for a multi-compartmental knee replacement.

Though Saleh in view of Bradbury does not explicitly contemplate a uni-compartmental knee replacement, it would have been obvious to one having ordinary skill in the art to apply the teachings of Saleh in view of Bradbury to a uni-compartmental knee replacement, depending on the type of implant required for an individual patient (see for example US Patent Application Publication No. 2005/0043807 A1 to Wood). It also would have been obvious to one having ordinary skill in the art at the time of the invention to include that the implant can be configured to alter the load bearing ability relative to the joint, in order to fully customize the implant, as taught by Bradbury. The examiner notes that the limitation “can be” appears to imply that the claim language is not required to meet the claim.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELISSA MONTANO whose telephone number is (571)270-5785. The examiner can normally be reached on Monday-Friday 8:00AM-5:00PM EDT.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Corrine McDermott can be reached on (571)272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MM

/Bruce E Snow/
Primary Examiner, Art Unit 3738